

<b>REPLY BRIEF</b>	Application #	08/981,665
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	First Inventor	CIPKOWSKI
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	Examiner	Grun, James Leslie
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**APPEAL FROM THE FINAL REJECTION**  
**MAILED DECEMBER 28, 2009**

**BRIEF IN REPLY TO THE EXAMINER'S ANSWER OF DECEMBER 7, 2010**

- A. THE EXAMINER'S ARGUMENTS RELATING TO THE REJECTION UNDER 35 U.S.C. § 112, FIRST PARAGRAPH, ARE MISPLACED AND TO THE CONTRARY SHOW THAT THERE IS ADEQUATE DISCLOSURE SUPPORTING THE CLAIMED LIMITATION

In the Examiner's Answer (herein cited as "Answer"), the Examiner maintained a rejection of Claims 16, 18 and 19 under 35 U.S.C. §112, first paragraph, in particular with regard to language in Applicants' claims directed to "a sample **contacting** portion necessarily **on the exposed surface** (i.e., front) **of the test strip** so that liquid sample flows through the sample opening in the thin flat member strip holder and contacts the **exposed surface** (i.e., front) of the sample portion directly beneath (i.e., registering with) the opening." See Answer, page 4, bottom paragraph (emphasis by Examiner). However, the arguments that the Examiner relies upon to support this contention once again show that his position is completely unfounded and Applicant's specification unambiguously shows these claimed features to one skilled in the art.

As an initial argument, the Examiner cites the case of *In re Ruschig*, 379 F.2d 990, 154 U.S.P.Q. 118 (C.C.P.A. 1967) for the misplaced allegation that "one cannot disclose a forest in the original application, and then later pick out a tree out of the forest and say 'here is my invention.'" Answer at page 5. In this case, however, it is the Examiner that cannot see the forest for the trees. In the first place, the *Ruschig* case cited by the Examiner is inapposite and, if anything, supports Applicant's position that the claim language has been adequately described for purposes of the written

description requirement under 35 U.S.C. §112. Contrary to the present case, in *Ruschig*, the issue was not a simple mechanical aspect of an invention such as a conventional test strip which fits into Applicant's claimed test card, but to a benzene sulfonyl urea chemical compound for use as oral medications to control diabetes, namely 13. N-(p-chlorobenzenesulfonyl) -N'-propylurea. The original patent application included claims for numerous specific chemical compounds, but did not specifically disclose 13. N-(p-chlorobenzenesulfonyl) -N'-propylurea. Accordingly, when the Applicants attempted to claim this compound, the claims were rejected under 35 U.S.C. §112, first paragraph, on the grounds that this specific chemical compound had not been described in the original specification.

The issue that was thus on appeal in *Ruschig* was Applicants' argument that although the original specification did not disclose 13. N-(p-chlorobenzenesulfonyl) -N'-propylurea, claims to this compound were supported because one skilled in the art would be enabled by the specification to make the new compound. This position was rejected by the C.C.P.A., holding that Applicants' argument "presumes some motivation for wanting to make the compound in preference to others. While we have no doubt a person so motivated would be enabled by the specification to make it, this is beside the point for the question is not whether he would be so enabled but whether the specification discloses the compound to him, specifically, as something appellants actually invented. We think it does not." 379 F.2d at 995, 154 U.S.P.Q. at 123.

To the contrary, in the present case, the specification clearly and unambiguously describes the claimed test card which includes a conventional test strip and does so in such a manner as to specify that the test strip sits below a test card which has sample

openings directly above a sample contacting portion of the test strip. This is clearly and unambiguously shown in Applicant's specification which describes and shows a conventional test strip, and also shows how the test strip fits into the test card such that the sample contacting portion of the test strip is directly below a corresponding opening in the test card. As Applicant has previously pointed out, this can easily be observed, e.g., by comparing Figs. 11 (front of the test card showing top ply 47 which fits over the test strips) and 12 (showing of test strips in ply 45 just below the front of test card). The specification also describes "sample openings 51" in the claimed test card through which "the liquid test specimen is able to contact the absorbent or sample portions of the test strips." See Applicant's specification, page 12, lines 7-9. Finally, even the Examiner concedes that the specification discloses that the sample passes through a sample opening in the test card onto the "absorbent or sample portions of the test strip", and thus it does not take a genius to determine that the sample then contacts the sample contacting portion of the test strip. Accordingly, unlike the case in *Ruschig*, the present subject matter is clearly, unambiguously and specifically disclosed in Applicant's specification. Thus, the Court in *Ruschig* would have immediately recognized that the present claims are adequately defined under 35 U.S.C. §112.

Instead, the Examiner's rejection appears to be based on a desire to subject the ordinary and plain meaning of the claims, which is clear and unambiguous, to unreasonable speculation that is improper with regard to the written description analysis. To make a simple analogy, suppose Applicant's specification described a "conventional piece of paper" and disclosed a covering over the paper which had a sample opening through which a sample was introduced so as to contact the paper. No

doubt, the present Examiner would object to such a description on the basis that “conventional piece of paper” was subject to “a broad range of possible designs” and “multiple possibilities,” including whether it had “conventional backing” or “sandwiching with plastic”, whether “the sample portion may only be the cut end”, and perhaps even whether it was made in the US or China where standards might differ and the type of pulp used in the paper might differ. Such positions would be as ridiculous as the Examiner’s position in this application.

In short, the Examiner concedes that Applicant’s specification discloses a test card wherein a specimen “is able to contact the ‘absorbent or sample’ portions of the test strip through the sample openings of the card,” (see Answer, sentence bridging pages 4 and 5) and the Examiner’s rejection is based solely on his peculiar view that Applicant did not disclose “guidance in the specification for certain particulars in the test strip structure.” See Answer at page 4. The present claims clearly and unambiguously are shown in Applicant’s specification, and the Examiner’s misguided position with regard to the written description requirement must be overturned.<sup>1</sup>

Accordingly, Applicant submits that the claims are entirely proper under Section 112 and that the Examiner’s rejection on this basis should be reversed.<sup>2</sup>

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<sup>1</sup> See also *In re Wright*, 9 USPQ2d 1649 (Fed. Cir. 1989), cited in Applicant’s Appeal Brief and not commented on by the Examiner, wherein under similar circumstances, the Federal Circuit reversed a written description rejection and held that the Board’s position that the disputed claim words were open to different interpretation “went to the *scope* of the phrase rather than the support for it and was deemed an irrelevant inquiry.” 9 U.S.P.Q.2d at 1651.

<sup>2</sup> The Examiner has withdrawn the previous objection to Claim 16 under 35 U.S.C. §112, second paragraph.

B. THE EXAMINER'S REJECTION UNDER 35 U.S.C. § 103(A) CONTINUES TO  
FOCUS ON A COMBINATION OF REFERENCES, DESPITE THE FACT THAT  
THE REFERENCES WHEN COMBINED STILL DO NOT TEACH OR SUGGEST  
THE CLAIMED LIMITATIONS

In the Examiner's Answer, the Examiner maintained the rejection of Claims 16, 18 and 19 under 35 U.S.C. §103 (a) as allegedly being unpatentable over May et al. PCT application WO 88/08534 in view of Sun et al. (US 5,238,652) and further in view of Boger et al. US 4,518,565. Once again the Examiner focused on his position that these references could be combined to show all of the elements of Applicants' claims. In Applicants' Appeal Brief, it was pointed out that this position was unfounded because since not all of the elements of Applicants' claims were disclosed in the prior art references, even a combination of those references would **not** give the present claims. In other words, Applicants has previously pointed out that in the case of where the claim was "A + B + C", a rejection could only be based on a combination of references if references disclosing elements "A", "B" and "C", respectively, could be located. However, where, as here, one of the elements used in the combination of reference was missing, the Examiner could not develop such a rejection merely by combining references. The Examiner completely missed this point and once again repeats the false allegation of the original Final Rejection that Applicants' argued that "there are no specific suggestions to combined the references". See Answer at page 16.

The Examiner further goes on to argue erroneously that Applicants "cannot show nonobviousness by attacking the references individually when the rejections are based on combinations of references." See Answer at page 19. The Examiner thus fails to recognize that Applicants have argued that the central failing of the rejection is that the Examiner has failed to point to the presence of the particular claimed elements in any of the cited references, and thus there is nothing to combine which would give Applicants' claimed invention. Finally, in his response regarding the obviousness rejection, the Examiner incomprehensibly relies on his position regarding Section 112 and refers to "specifics regarding the test **strip** structural limitations" (see, e.g., Answer pages 18-19), when such arguments clearly are irrelevant to Applicants claimed test **card** or the Section 103 rejection. The bottom line is that the Examiner's position with regard to the May reference is in error, and as a result, the Examiner's rejection must fail.

As was previously pointed out in Applicants' Appeal Brief, none of the references cited by the Examiner (May WO 88/08534, Sun US 5,238,652 or Boger US 4,518,565) discloses or suggests Applicant's claimed test card, namely one which houses one or more immunoassay strips wherein the liquid specimen passes through the opening directly above the sample contacting portion on the front of the test strip and then proceeds via capillary action along the strip to the test portion wherein an analyte in the specimen may be visually determined through another opening in the test card. Even further, the May reference which is central to the Examiner's position, actually **teaches away** from the present claims because in the relevant embodiment, the device **covers up** in all cases the front surface of the test strip and **prevents** the sample from contacting the test strip on the front surface of the strip.

In particular, as best shown in Figs. 11 and 12 in May, this reference discloses a device wherein the fluid sample is directed through opening 601 which is not a sample contacting portion of a test strip (element 606) and is in fact not even directly over the test strip 606 itself. Instead, the fluid sample is contacted only through the end of the test strip 606 which is blocked from receiving a fluid sample on the front end of the test strip. May thus discloses a device which is fundamentally different than the claimed invention because there is no sample contacting portion on the front surface of the test strip and instead there is a sample opening which only exposes the end of a porous member through which the specimen must pass before it can even contact the absorbent part of the test strip.

Although the Examiner alleges in the Answer that the May references discloses Applicants' claimed configuration and makes vague references to the Figures in May, he concedes that May does not "teach the immunoassay means for determination of drugs of abuse as instantly disclosed and claimed" (Answer, page 9, lines 12-13). Moreover, a simple review of those figures in May shows that **none** of the embodiments therein discloses Applicants' claimed configuration wherein a test card has a plurality of sample contacting openings which expose sample contacting portions in the test strips and through which the sample will pass and make initial contact with the exposed test strip surface below the sample contacting openings.

In particular, Figs. 1 and 2 of May merely show the assay test strip 10 and are thus of no relevance to Applicants' invention. Figs. 3, 4 and 5 show the device of the first embodiment, which includes section 12 which contains the reagents used in the sample analysis and a section 14 wherein the analyte may be determined. However,



unlike the present claims, this embodiment has a front surface with an opening **only** over the area wherein the analyte will be determined and **not** over the portion wherein the sample will be contacted with the reagents used in the analysis. Instead, the device is configured as shown in Figure 5 wherein the sample opening is shown at the bottom end 35 of the device and is a lateral opening to ensure that the sample is received at the end of the test strip (11) and **not** at its front surface as is the case in Applicants' device. See May, page 20, lines 25-28 wherein it is stated that: "In operation, the bottom end 33 of the body 30 is immersed in a liquid sample (eg urine) so that the liquid sample **can be absorbed by the bottom end 11** of the test strip." (emphasis added). In other words, May discloses the type of device wherein a sample is introduced at the **end** of a test strip, and not at a sample contacting portion on the front surface of the test strip as is the case with Applicants' test card device. Applicants' claimed test card comprises an improvement over the May reference because it provides a much more efficient and effective way of initiating the immunoassay reaction and obtains a quicker and more accurate result than the configuration shown in May. Because May discloses introduction of the sample at the **end** of the test strip which is a direction divergent from the presence of the opening on the front surface as in Applicants' invention, it **teaches away** from the present claims.<sup>3</sup>

Further, none of the other embodiments of May disclose or suggest Applicant's improved configuration, and instead uniformly show a device wherein the sample is introduced at the end of the test strip and not the front surface. In particular, in the

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<sup>3</sup> See *In re Gurley*, 31 U.S.P.Q.2d 1130, 1131 (Fed. Cir. 1994), cited in Applicant's Appeal brief and not commented upon by the Examiner in the Answer, wherein the Court stated "A reference may be said to teach away when a person of ordinary skill, upon reading the reference, . . . would be led in a direction divergent from the path that was taken by the applicant."

embodiment of Figs. 6-7, the sample is directed through an opening 202 so as to introduce the sample at the end of the test strip, and not directly on the front surface of the test strip which remains covered. In Figs. 6-7, there is a sample member 506 which receives the sample at the end, and this transfers the sample to the dry porous carrier 510 which contains the identifying reagents and will be used for the assay. As observed in Fig. 8, there is no opening over a sample contacting portion of the test strip, and although two openings are shown in this embodiment, 508 and 509, both are openings relating to the results concerning the assay and **not** wherein the sample will be initially contacted. See May, page 24, lines 20-25 ("After the appropriate time, the user can observe the test strip through apertures 508 and 509 and can ascertain whether the assay has been completed by observing the control zone through aperture 509, and can ascertain the result of the assay by observing the second zone through aperture 508.")

With regard to the embodiment shown at Figs. 11-12 in May, which is described above and in more detail in Applicant's Appeal Brief, this is a device wherein the sample is **not** introduced directly to the test strip, but to a receiving member at its adjacent end 602, and the test strip is **blocked** at its front surface from receiving the sample. In fact, a backing sheet 607 is provided in the upper surface of the device "**to prevent ingress of moisture or sample into the casing.**" See page 27, lines 27-31 (emphasis added). In other words, as Applicant has pointed out, the device in May **prevents** contact on the front surface of the test strip.

Finally, the embodiments shown in Figs 13-14 mirrors the embodiment shown in Figs. 3-5 wherein there is only a sample opening 704 at the end of the device and **not** the front surface, and the only opening on the front surface is opening 702 wherein the results of the test are observed. See May, page 29, lines 4-13.

In short, each and every embodiment disclosed in the May reference thus directs one skilled in the art **away** from the present invention because the fluid is contacted at the lower end of the test strip and **not** at its front surface as in Applicant's claims, and moreover **actively blocks the front surface** of the test strip from receiving the sample.

Moreover, the Examiner in his Answer cannot point to any disclosure in the cited Sun or Boger references which could be added to overcome the deficiencies in the May reference which teaches away from the present claims. In particular, the Sun reference also does not disclose a test card with a sample contacting portion on the front surface of the test strip, and even further, the Examiner has previously conceded that the Sun reference does not have openings exposing the test portions of the strips. See, e.g., the prior Decision on Appeal in this application (March 31, 2003), at page 4. Instead, the Examiner appears to cite Sun because it discloses "that strips for such drug of abuse analytes may be configured in a parallel arrangement for simultaneous testing of multiple analytes" (see Answer, page 9, bottom paragraph), but this of course is totally irrelevant to the placing of sample openings over the sample contacting portion on the front surface of a test strip in the present claims

Further, the Examiner merely cited the Boger et al. reference for the fact that it shows “ridges defining slots to facilitate parallel test strip arrangement” (see Answer, page 13, lines 4-5) and conceded that Boger does not “specifically teach strips for immunoassay of drugs” (See Answer, page 12, bottom. Once again, Boger is totally irrelevant to Applicant's configuration of a test card having sample openings over an exposed sample contacting portion of s test strip and this cannot be added to overcome the deficiencies pointed out above with regard to the May reference.

Applicant thus submits that the cited references, either singly or in combination, do not disclose or suggest Applicant's claimed invention, and that the Examiner's rejection for obviousness under 35 U.S.C. §103(a) is respectfully traversed and should be reversed.

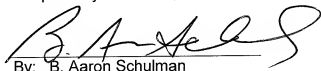
C. CONCLUSION

For the foregoing reasons, Applicant submits that the present claims are supported clearly and unambiguously in the specification pursuant to 35 U.S.C. §112, first paragraph, and that the Examiner's rejection under this provision is misplaced and should be reversed. Further, since none of the cited prior art references disclose or suggest the specific claimed features of Applicant's invention, and in fact **teach away** from the claimed subject matter and would **prevent** the operation of the present claims, the Examiner's rejection under 35 U.S.C. §103(a) is similarly unfounded and should be reversed.

Therefore, Applicant requests that the Board reverse the decision of the Examiner, and instruct the Examiner to withdraw the remaining rejections so that this application can be passed on to allowance.

Respectfully submitted,

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